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Implementing AI in pharmaceutical manufacturing

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Executive Summary

A pivotal time for a life-saving industry

Today's pharmaceutical manufacturing businesses face a raft of unique challenges.

While advances in drug development have accelerated dramatically in recent years, manufacturing processes have struggled to keep pace – for a number of intertwined reasons:

- Production lines struggle to adapt quickly to new product launches and dynamic supply planning
- Quality control and quality assurance processes remain largely manual and time-consuming
- Supply chains have proven vulnerable to global disruptions [1]
- Changing regulatory landscape bringing up further complexities to implement and scale AI

When manufacturing processes are slow to adapt or supply chains falter, delays in drug availability increase healthcare costs and lead to severe consequences for patients. That means these challenges impact not only operational efficiency, but patient access to life-saving medication.

The industry therefore needs widespread transformation to make pharmaceutical manufacturing more efficient, robust and reliable.

With rising economic constraints putting an emphasis on agile, regulation-friendly digital solutions [2], artificial intelligence (AI) stands out as a possible solution to the sector's challenges – with breakthroughs making scalable implementation more feasible and more impactful than ever before [3].

AI can transform pharmaceutical manufacturing from top to bottom.

Machine learning tools can support the optimisation of production processes, accelerate the implementation of predictive maintenance, enhance quality control, increase the robustness of supply chains, and – with the help of generative applications – streamline the process of writing regulatory documentation.

Together, these applications of AI promise not only to modernise pharmaceutical manufacturing, but to also improve product quality, reduce costs, and enable greater patient access to critical medication.

Purpose

This whitepaper serves as a guide to AI's potential for transforming pharmaceutical manufacturing operations, with two primary contributions to the topic.

First, it provides a detailed overview of AI's current and potential applications in pharmaceutical manufacturing by:

- Mapping where AI can create value across manufacturing operations
- Quantifying benefits and outcomes from real-world implementations
- Analysing how AI enhances key processes
- Examining case studies from leading pharmaceutical companies

Second, we propose practical guidance on implementing AI in a pharmaceutical manufacturing setting, including:

- A process framework for AI development and validation in GxP-regulated environments
- A step-by-step approach for introducing AI into manufacturing operations
- Proven strategies to overcome common challenges
- Successful practices derived from successful implementations

The insights and recommendations presented in this whitepaper are grounded in academic research, documented case studies, and the practical experience of Zühlke and the University of St.Gallen.

Audience

This whitepaper is designed for pharmaceutical industry professionals looking to understand AI's real-world potential in manufacturing and quality control – and how to successfully implement relevant solutions.

Introduction

A seismic paradigm shift

Pharmaceutical manufacturing is transforming.

Systems that have served the industry for decades are now creaking under the weight of fresh agility, efficiency, and quality control demands. With the COVID-19 pandemic, international trade uncertainties and increasing cost pressure bringing supply chain vulnerabilities and legacy constraints into sharp focus, the need for change is clear. In today's manufacturing environment...

- One-track production lines need extensive downtime to change output
- Quality control relies on inefficient, manual batch testing
- Deviation tracking and root cause analysis are time-consuming, especially in manufacturing, due to fragmented, disconnected data
- Production decisions rely on historical data rather than real-time insights
- Automation remains limited, with many machines/equipment still operated manually or semi-automatically

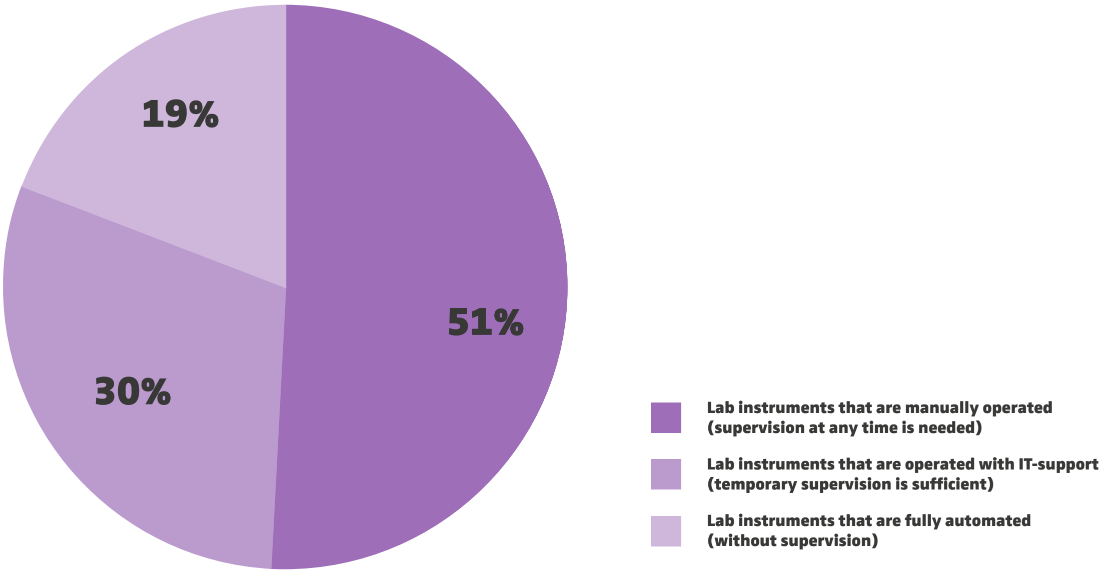

Figure 1: Automation levels of lab instruments (n = 163) (Source: St.Gallen QC Lab Benchmarking)

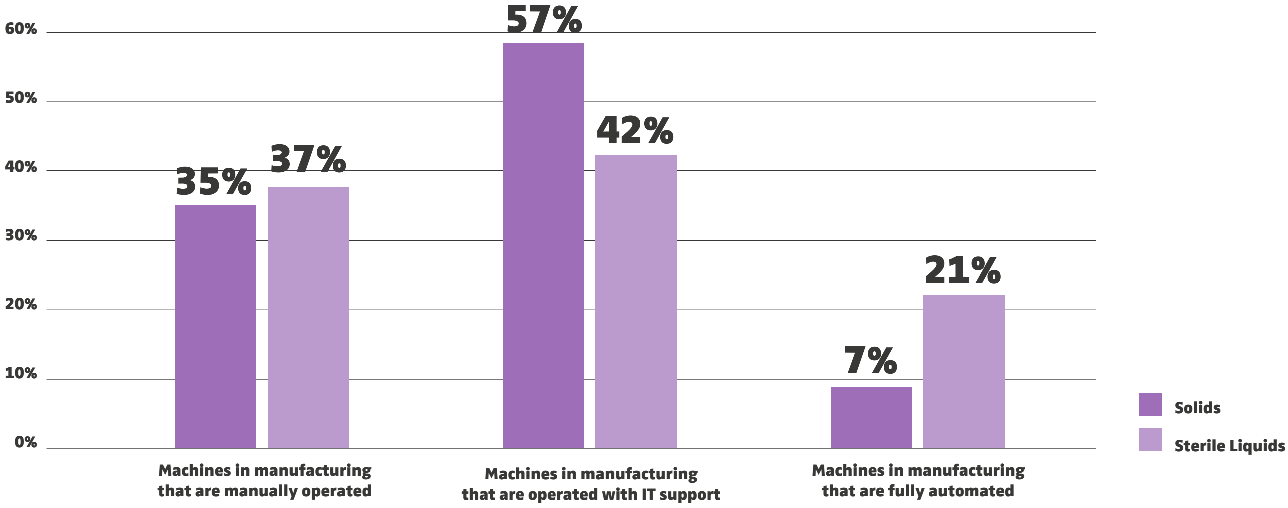

Figure 2: Automation levels of manufacturing machines across value stream steps (formulation, primary packaging, secondary packaging) for solids (n = 39) and sterile liquids (n = 47) (Source: St.Gallen OPEX Manufacturing Benchmarking)

These are slow, fallible and reactive processes. But there is an alternative.

Imagine a manufacturing facility where production lines automatically adjust their parameters based on real-time quality control data. Where machines predict their own maintenance needs before failures occur. And where supply chain decisions are guided by AI systems that forecast demand with clairvoyant accuracy.

This AI-enabled paradigm shift isn't sci-fi; it's already powering some of the world's biggest pharmaceutical companies – and it's fast becoming what separates the industry's leaders from its laggards.

According to strategy& «pharma companies that industrialize AI use cases completely across their organizations have the potential to double today's operating profits by boosting revenues and reducing costs. We expect that this industrialization process will begin to be fully realized by companies prioritizing AI by 2030.» [4].

The message here is obvious: AI adoption in pharmaceutical manufacturing is not just an opportunity for improvement – it's becoming a competitive necessity.

In this paper, we'll explore why, where, and how AI can upturn traditional processes in the sector.

Process problems

Mapping today's manufacturing challenges

Before we explore the ways in which AI can help optimise pharma manufacturing, we need to understand where the sector's challenges, inefficiencies and vulnerabilities currently lie.

'Manufacturing' is a catchall term for a range of processes that run the full gamut of medicinal production. As such, modern pharmaceutical manufacturing faces an equally varied range of persistent challenges that limit improvements from operational efficiency to resources and labour supply.

We have identified six key issues impacting the industry in 2025:

Quality control (QC) and quality assurance (QA) complexities

Ensuring consistent product quality is crucial in the pharmaceutical industry. However, QC and QA processes are often labour-intensive and time-consuming, involving extensive testing and documentation. Traditional approaches rely on manual sampling and data entry, where human error and quality deviations can come into play.

These deviations can delay product releases – and result in costly batch rework or rejection. Moreover, the absence of any real-time quality monitoring limits manufacturers' ability to adjust production parameters instantaneously, further reducing process efficiency.

Production inflexibility

Pharmaceutical manufacturing lines are typically designed for large-scale production of specific drugs. As a result, switching between products (or adjusting batch sizes) to meet fluctuating demand is both time-consuming and expensive [5].

This lack of agility can lead to either drug shortages or excess inventory, meaning that – as the industry shifts towards more personalised therapies and smaller batch production [6] – these legacy systems are growing increasingly unfit for purpose. Moreover, dynamic shift planning remains poorly integrated with production scheduling, making it difficult to adapt workforce allocation in real time based on fluctuating production priorities, equipment availability, or unexpected disruptions – leading to inefficiencies and underutilisation of resources.

Workforce limitations

The industry is grappling with workforce-related challenges tied to an aging workforce and a shortage of skilled labour in new technologies. Many companies lack the internal expertise to deploy and maintain more advanced, emergent systems, while upskilling existing staff is often deemed too costly and time-consuming. These limitations are further exacerbated by rigid planning processes that restrict the ability to adjust workforce deployment in response to changing production needs – reducing responsiveness and making it harder to fully utilise available skills. This issue then compounds, creating further barriers to modernisation.

Regulatory complexity

The pharmaceutical sector is subject to incredibly strict regulations, including current Good Manufacturing Practices (cGMP) [7] and Good Automated Manufacturing Practices (GAMP) [8] alongside many others. Introducing new technologies like AI or automation therefore requires thorough validation and compliance processes.

These regulatory obligations can stifle innovation, as approvals are often time-consuming and resource intensive. For example, Annex 11 highlights the importance of end-to-end lifecycle management of computerized systems, taking into account patient safety, product quality, and data integrity [9].

Resource optimisation

Without predictive insights or advanced monitoring, many companies operate below optimal efficiency. Inefficient large-batch manufacturing methods alone have been estimated to cause up to $50 billion USD in annual waste [10].

The inability to anticipate maintenance needs, optimise production schedules, or respond in real time to process deviations leads to unnecessary downtime, higher energy consumption, and excess material usage – all of which erode profitability.

Supply chain vulnerability

Recent global events have highlighted the fragility of pharmaceutical supply chains. During the COVID-19 pandemic, for example, over 80 countries imposed export restrictions on essential medical goods, severely impacting drug availability worldwide [1].

Traditional supply chain management, which often lacks real-time visibility and relies on strict planning, is sluggish to respond to external changes and threats. Limited transparency across suppliers and production sites, meanwhile, further complicates the ability to anticipate and mitigate major and minor disruptions.

Key takeaways

Pharmaceutical manufacturing today faces several major hurdles, including labour-intensive quality control, inflexible production lines, and a shortage of skilled workers. Strict regulations inadvertently act to slow innovation, while outdated systems often lead to inefficiencies and waste.

Supply chains can be fragile – with a lack of real-time visibility – making it harder to respond to disruptions. These challenges highlight the need for smarter, more agile operations.

Intelligent efficiencies

Outlining AI's potential

Each of the challenges listed above present an opportunity for new technologies like artificial intelligence to help rethink, revamp and revolutionise the way we think about manufacturing processes.

AI is often touted as the be-all and end-all solution, but to set realistic expectations we must first get to grips with what artificial intelligence actually means in an industrial context.

AI is an umbrella term encompassing a range of technologies – from simple statistical models like linear regression, to advanced systems like deep neural networks and Large Language Models (LLMs). As applications, these systems can work together to perform complex tasks like classification, prediction, anomaly detection and content generation.

In pharmaceutical manufacturing, AI can e.g. automate real-time process adjustments, predictive maintenance, visual inspection, production scheduling optimisation and intelligent access to SOPs and GMP guidelines via natural language interfaces.

SOPs, GMP and GxP

SOPs (Standard Operating Procedures) are detailed, written instructions that outline how specific tasks must be performed to ensure consistency, safety, and regulatory compliance.

GMP (Good Manufacturing Practice) refers to the industry's core quality standard, ensuring that products are consistently produced and controlled according to strict quality requirements.

SOPs and **GMP** fall under the broader umbrella of **GxP** – a collection of quality guidelines and regulations (like Good Laboratory Practice and Good Clinical Practice) that govern regulated industries.

Here are six AI use cases that can help in this setting:

1. Process optimisation

AI-driven process optimisation tackles the rigidity of traditional manufacturing systems head-on. Conventional approaches often rely on trial-and-error or one-factor-at-a-time parameter tuning. In contrast, AI models analyse thousands of sensor inputs in parallel, enabling multivariable optimisation in real time.

These systems support adaptive process control, which automatically adjusts to production fluctuations to reduce variability, optimise titer and yield, and ensure consistent product quality – all without the need for human intervention. This level of agility is especially critical as the industry moves toward more personalised therapies and smaller batch sizes.

2. Predictive maintenance

Unplanned equipment downtime and inefficient maintenance scheduling are persistent pain points in pharmaceutical production. AI-based predictive maintenance systems analyse both historical and real-time equipment data to detect early signs of wear or failure. Maintenance can then be scheduled proactively, reducing unexpected breakdowns and extending equipment lifespan.

AI also enhances overall resource efficiency by optimising production schedules. This lowers energy consumption, and minimises material waste – key drivers of cost reduction in batch manufacturing environments, where inefficiencies can result in billions of dollars in annual losses.

3. Quality control and quality assurance

QC and QA processes are traditionally labour-intensive, time-consuming, and prone to variability. AI offers a step change in both speed and consistency. Computer vision-enabled systems, for example, can conduct high-precision visual inspections across 100% of pr oducts, far exceeding the accuracy and consistency of manual checks. In addition, AI-powered analytics can streamline deviation tracking and accelerate root cause analysis by identifying patterns across fragmented datasets – helping teams respond faster and reduce downtime.

Beyond inspection, AI can analyse production and deviation data to proactively predict – and prevent – quality issues. Real-time monitoring facilitates this continuous quality assurance, which moves the model from batch-based, retrospective testing to inline control.

Generative AI further streamlines laboratory operations by automating a range of documentation tasks, including drafting SOPs, protocols, and investigation reports. It also supports method harmonisation, compliance validation, and onboarding processes – all of which can accelerate learning curves and reduce reliance on manual effort.

4. Supply chain intelligence

Global supply chain disruptions have made resilience a top priority. AI enables smarter, more adaptive supply chain operations by bringing diverse data sources – like market demand, supplier reliability and geopolitical factors – into a single source of truth.

AI models can then use those signals to forecast demand more accurately, identify emerging risks and recommend mitigation strategies such as alternative sourcing or rerouting. This dynamic planning allows pharmaceutical companies to respond more effectively to shocks – improving reliability, reducing waste, and maintaining continuity of drug supply. To enable this agility, it is critical to maintain a digital twin of the inventory that not only reflects real-time stock levels and flows, but also includes regulatory attributes aligned with product filings across markets.

5. Compliance AI

Compliance AI tools can navigate the industry's complex regulatory landscape by extracting relevant content from SOPs, audit trails, and deviation reports.

These systems automate documentation generation, support traceability, and reduce the manual workload tied to compliance efforts. By improving accuracy and reducing time-to-approval, Compliance AI helps accelerate the integration of new technologies into validated environments.

6. Human resources optimisation

AI supports more effective human resource management through intelligent scheduling, capacity planning, and workforce balancing by forecasting production needs and aligning them with staff availability. In 'review by exception' environments, AI tools can monitor operations continuously and alert human operators only in the event of any anomalies – freeing up employees to focus on high-value, decision-driven tasks.

Key takeaways

AI presents a powerful opportunity to transform pharmaceutical manufacturing. Real-time process optimisation, predictive maintenance, and automated quality control can reduce errors and improve efficiency.

The technology's ability to predict behavior can also aid supply chain resilience, while intelligent document handling can streamline compliance and enable smarter workforce management.

AI in action

Real-world industry case studies

AI's potential in a pharmaceutical setting is already being realised by some of the world's most forward-thinking companies.

Here are three successful examples of AI-enabled process optimisation:

Pfizer

Advanced manufacturing intelligence for bioreactor optimisation

Background

Pfizer sought to improve bioreactor performance in the production of antibody drug conjugates (biologics) – specifically targeting inefficiencies and variability in the fermentation process.

The highly complex and dynamic nature of bioreactors, where numerous interdependent variables influence yield, posed a major challenge. Traditional methods for monitoring and adjusting bioreactor parameters proved insufficient, meaning that engineers were spending excessive amounts of time manually analysing fragmented data sources to make operational decisions [11].

Solution implementation

Pfizer partnered with Amazon Web Services (AWS) to develop an advanced manufacturing intelligence system using the Industrial Internet of Things (IIoT) and machine learning. The solution used AWS Industrial Edge Services to aggregate and analyse bioreactor data in real time.

Regression-based machine learning models were deployed to predict critical process parameters and identify optimal operating conditions. The system captured time-series data directly from bioreactors, performed edge computing for real-time processing, and leveraged a digital twin of the manufacturing process for simulation and optimisation [11].

Understanding the Industrial Internet of Things (IIoT)

The Industrial Internet of Things (IIoT) refers to the network of interconnected sensors, devices, and systems used in industrial settings to collect, share, and analyse data in real time.

In pharmaceutical manufacturing, IIoT enables machines, equipment, and production lines to communicate and generate valuable insights. By connecting physical operations to digital systems, IIoT lays the foundation for smarter, more responsive, and data-driven manufacturing environments.

Results

Pfizer enhanced its ability to monitor and optimise bioprocessing operations. The company gained greater visibility into bioreactor performance, making it easier and faster to surface optimisation opportunities while also improving manufacturing intelligence capabilities [11].

Gilead
Enterprise AI for manufacturing knowledge management

Background

Gilead's Pharmaceutical Development and Manufacturing (PDM) division faced critical challenges in accessing and managing scattered data across nine disparate enterprise systems – and a multitude of knowledge repositories. This fragmentation hindered staff productivity and slowed the development of new therapeutic treatments, as employees struggled to retrieve relevant manufacturing and development information [12].

Solution implementation

Gilead implemented an enterprise AI-powered search and knowledge management platform. The system integrated data from a range of sources, used machine learning to enrich metadata, and applied natural language processing (NLP) for more accurate search capabilities. The resulting solution centralised access to manufacturing and development data, enabling predictive analytics and creating a unified data platform for operational insights [12].

Results

Gilead's AI solution delivered significant operational benefits. It reduced the time employees spent searching for manufacturing information by approximately 50% – and substantially decreased the burden of manual data management tasks. Similarly, analytics delivery was accelerated dramatically, from timelines of up to a year to just a few business days. The platform also improved compliance readiness through better data organisation and traceability [12].

Merck & Co.
AI for reduction of false rejects

Background
Merck encountered persistent challenges with false rejects during pharmaceutical product manfacturing. False rejection – where quality control systems incorrectly classify acceptable products as defective – affects anything from 1% to as much as 45% of product lines, resulting in significant waste and estimated costs of up to $740 M per year. Minimising these errors while maintaining stringent quality standards was a critical objective for Merck's operations [13].

Solution implementation
To tackle this challenge, Merck partnered with Amazon Web Services (AWS) to develop an AI-powered inspection and analytics platform based on Amazon SageMaker. The solution integrated inspection machine image data through AWS DataSync, and applied advanced machine learning models to identify the patterns that lead to false rejects. A key innovation in this approach was the use of Generative Adversarial Networks (GANs) to synthetically generate rare defect images. This helped develop more robust training datasets without having to wait for actual defects to occur in production [13].

What are Generative Adversarial Networks (GANs)?

A Generative Adversarial Networks is a type of AI application used to generate realistic synthetic data. GANs require two neural networks – a generator and a discriminator – that work against each other, where the generator creates new data and the discriminator evaluates it for authenticity.
In pharmaceutical manufacturing, GANs can be used to simulate edge cases, helping improve quality control accuracy without affecting real-world production.

Results
Following full deployment, the AI solution achieved a 50% reduction in false reject rates. This improvement significantly lowered waste and production costs while increasing throughput across manufacturing lines. The system also enhanced Merck's understanding of the root causes of false rejects, allowing for targeted process improvements. By leveraging synthetic defect data, Merck was able to strengthen its quality control systems without compromising ongoing production activities [13].

Key takeaways

Leading pharmaceutical companies are already harnessing AI to drive real-world improvements in manufacturing.

- **Pfizer** has optimised bioreactor performance using real-time analytics and digital twins, cutting manual analysis time.
- **Gilead** has streamlined its knowledge management with an AI-enabled platform, halving search times and speeding up analytics.
- **Merck & Co.** is using machine learning and synthetic data to reduce false reject rates by as much as 50% using, cutting waste and boosting efficiency.

Compliance and culture

AI implementation considerations and requirements

Deploying AI solutions in any industry requires a rich understanding of the requirements, risks, and ramifications – and this is especially true in pharmaceutical manufacturing, where mistakes cost lives and regulatory scrutiny is fierce.

So, before we discuss how to design a successful AI rollout, we must first address these considerations across two vectors: regulatory and organisational.

Regulatory considerations

The implementation of AI systems in pharmaceutical manufacturing must align with both long-standing regulatory expectations for computerised systems and ever-evolving requirements specific to AI technologies.

The U.S. FDA's discussion paper on Artificial Intelligence in Drug Manufacturing [13], for example, outlines several critical factors that manufacturers must address when integrating AI into regulated environments. These include model validation, lifecycle management, data integrity, and the implications of adaptive or self-learning systems.

Quality system integration

A key principle of regulatory compliance is the integration of AI into existing quality systems. According to ICH Q7 [15], computerised systems must be validated in accordance with their complexity, diversity, and criticality. Due to their algorithmic complexity, reliance on large datasets, and potential to evolve, AI systems present new dimensions to this requirement.

However, most current AI applications in pharmaceutical manufacturing are not adaptive in real time. They are typically version-controlled, static models that do not continuously learn post-deployment. This makes integration and validation within a GMP framework more manageable, provided that these systems are well designed and properly documented from the outset.

Validation and qualification requirements

AI-enabled systems must adhere to the traditional validation lifecycle, adapted to address their unique characteristics while remaining consistent with GMP principles. ICH Q7 [15] outlines four essential stages:

- **Design Qualification (DQ):**
  Ensuring that the AI system's architecture and design meet the intended operational requirements.
- **Installation Qualification (IQ):**
  Confirming that the system is installed correctly, in accordance with predefined specifications.

- **Operational Qualification (OQ):**
  Demonstrating that the AI functions as intended under simulated or controlled conditions.
- **Performance Qualification (PQ):**
  Validating that the AI operates reliably and reproducibly in the actual production environment.

The FDA also notes the growing need for regulatory guidance specific to AI, particularly regarding model lifecycle strategies, revalidation criteria, and how AI-driven process changes may affect product comparability. Ensuring transparency in how models are updated, versioned, and validated over time is critical for regulatory acceptance.

In a 2024 address, then FDA Commissioner Dr. Robert M. Califf highlighted the agency's commitment to developing strategies focused on AI lifecycle management:

"The FDA's approach to continuing to enable AI innovation includes the development and execution of a strategy with multiple components focused on building out infrastructure, methods, and tooling to identify safety operating parameters, standards, best practices, risk-based frameworks, and operational tooling for AI lifecycle management, including safety monitoring and management."

Data management and change control

Robust data governance is foundational for AI integration – especially when cloud-based systems are involved. Maintaining data integrity, clear audit trails and access control is essential to safeguard both product quality and compliance. One of the key challenges in AI implementation is in how to manage changes to models over time. Adaptive models and iterative retraining cycles, for instance, make it difficult to determine when a system's evolution constitutes a 'formal' process change [14, 15].

This ambiguity creates a compliance risk. Without clear internal thresholds for model updates, com-panies may unintentionally introduce unvalidated changes into their manufacturing process. To mitigate this, firms should develop structured change control protocols that define the following [14]:

- When an AI model version constitutes a new system requiring revalidation
- The criteria for regulatory notification based on the impact of changes
- How risk assessments will be conducted for AI-driven modifications

This proactive approach enables companies to keep regulatory alignment while benefiting from continuous improvement through AI.

Ongoing monitoring and control

Even when AI systems are not adaptive, ongoing monitoring remains essential. ICH Q7 emphasises that computerised systems must be periodically reviewed to ensure continued compliance. For AI, this monitoring should include performance drift detection, data quality assurance, and model output verification over time [14, 15].

Cloud-based AI systems also introduce unique risks. Many existing quality agreements with third-party providers do not sufficiently address AI-specific challenges like model version transparency, algorithm bias, or remote update controls. Pharmaceutical companies must therefore revise their control frameworks to explicitly manage these risks. This includes strengthening data governance, enhancing contractual oversight of cloud service providers, and regularly auditing both model behaviour and the supporting infrastructure [14].

Failure to proactively manage these aspects can result in both regulatory exposure and compromised product integrity. A forward-looking approach – one rooted in early collaboration between quality, IT, and regulatory affairs teams – is key to integrating AI safely and effectively within the highly regulated pharmaceutical landscape [8, 14].

Key takeaways

Successfully deploying AI in pharmaceutical manufacturing means meeting strict regulatory and organisational requirements. Key challenges include validating AI systems within GMP frameworks, managing data integrity, and controlling model updates over time.

While static models make validation more manageable, adaptive systems raise compliance issues. Robust data governance, structured change control protocols, interdepartmental cooperation, and continuous monitoring are therefore essential to ensure compliance and integrity.

Organisational readiness

Successfully implementing AI in the pharmaceutical industry requires more than just deploying new technologies – it demands a supportive organisational environment grounded in process proactivity.

Achieving sustainable innovation through AI depends on four foundational pillars [16]:

People and competences

People are central to safe and effective AI adoption in a regulated setting. Building AI capabilities requires not only hiring talent with deep technical expertise – like data scientists and machine learning engineers – but also ensuring that QA, regulatory, and domain specialists are actively involved and reskilled in order to future augment these technologies and incorporate into their daily work. This requires heavy organizational change management. Roles and responsibilities must be clearly defined, particularly regarding model validation, compliance oversight, and lifecycle management.

Many pharmaceutical organisations already operate internal AI teams within units such as Drug Discovery, Real-World Evidence (RWE), and Clinical Operations. These teams should be strategically leveraged beyond their core purpose. That might mean, for example, involving senior data scientists in hiring, establishing internal AI advisory groups, or facilitating knowledge exchange across functional lines.

While R&D applications may require specialised profiles, enterprise-wide adoption hinges on generalist AI professionals who understand both data science and regulated pharma operations. Establishing centralised AI consulting functions or Centres of Excellence can help standardise successful practices, provide regulatory-aligned support, and ensure AI initiatives align with business and compliance goals.

Meeting these needs requires strong, reliable leadership and a company-wide culture that values openness, curiosity, and transparency.

Data and governance

A critical pillar of any data-driven pharmaceutical organisation is robust data management. This requires mature data governance frameworks, well-established security and compliance protocols (e.g., GxP, HIPAA, GDPR), and clearly defined ethical standards for the collection, processing, storage, and deletion of data – particularly when handling patient-level data, clinical trial records, high-value intellectual property, or proprietary research outputs.

A solid data infrastructure – working within trusted data ecosystems – is indispensable here. Internal data stakeholders, including clinical operations, pharmacovigilance, and R&D teams, must not only be aware of applicable data handling policies, but also be equipped with tools and platforms that make compliance scalable, auditable, and user-friendly.

Beyond compliance, effective data management also drives operational efficiency. For example, electronic health record (EHR) datasets or real-world evidence (RWE) sources are often costly to license and prepare. Without centralised coordination, different teams may redundantly process the same datasets – resulting in duplicated effort, inconsistencies, and inefficiencies. In siloed data environments, teams may not even be aware that these datasets already exist.

Implementing an enterprise-wide data strategy – one that addresses data governance for source systems and data management for daily operations – enables visibility into available assets, ensures data lineage and access control, and facilitates cross-functional collaboration – from biomarker discovery to market access. This not only improves operational agility but also accelerates innovation by ensuring high-quality, trustworthy data is available, reusable, and actionable across the value chain.

Structure and process

Another key enabler of becoming a data-driven organisation is the establishment of transparent, well-defined processes that are supported by clear organisational structures. This is essential to realising the full potential of AI across pharmaceutical functions.

For instance, structured processes – like standardised AI use case intake and prioritisation, regulatory-aligned model validation pipelines, and centralised knowledge-sharing platforms – help ensure consistency, minimise duplication, and accelerate innovation. AI portfolio management frameworks also allow organisations to monitor progress, measure impact, and coordinate development efforts across departments. This is especially important when working with complex and high-cost datasets like RWE or clinical trial data. Such processes provide visibility into the organisation's data and AI capabilities, while also building trust by demonstrating measurable outcomes. When leadership and operational teams see tangible clinical, supply chain, or commercial benefits, it fosters adoption and promotes collaboration across traditionally siloed functions.

Infrastructure and technology

All of these capabilities depend on a reliable, fit-for-purpose technological foundation. Whether training predictive models using clinical development data or deploying real-time analytics for safety monitoring, pharmaceutical companies need systems that are secure, transparent, scalable, and easy to use.

That means data should be readily discoverable and interoperable across functions. Scientific experiments must be traceable, reproducible, and auditable. AI models should be deployable and maintainable without friction, enabling alignment with evolving data inputs and changing regulatory expectations.

Investing in AI-ready infrastructure is not just a technical necessity; it is a strategic imperative that acts as the bedrock for future innovation. The right infrastructure can help pharmaceutical organisations scale AI initiatives that support innovation, faster time-to-market, and improved patient outcomes.

Core systems supporting these efforts may include LIMS (Laboratory Information Management Systems), LES (Laboratory Execution Systems), MES (Manufacturing Execution Systems), QMS (Quality Management Systems), and ERP (Enterprise Resource Planning) platforms such as SAP – all of which must be tightly integrated into the AI development and deployment lifecycle.

Key takeaways

Organisational readiness requires skilled, cross-functional teams, robust data governance, clear processes, and scalable infrastructure. Pharma companies need to work to align their AI efforts with compliance and business goals, foster a collaborative culture, and ensure data is accessible and well-managed across teams and roles. Leadership support is vital.

Model behaviour

A robust AI implementation framework

Having addressed the various regulatory and organisational requirements, the next step is to establish a practical, robust framework for implementing AI in pharmaceutical manufacturing.

This framework must align regulatory compliance with technical realities to ensure GMP adherence and safe, scalable innovation. Successful AI deployment in GxP environments calls for a structured, end-to-end approach – spanning, Discovery, Alpha, Beta and Live phase. Throughout all phases, data and model-related activities such as design, development, model training, verification, robust deployment, monitoring, and continuous improvement are key. Figure 3 below shows how validation and qualification requirements can be addressed for AI based systems.

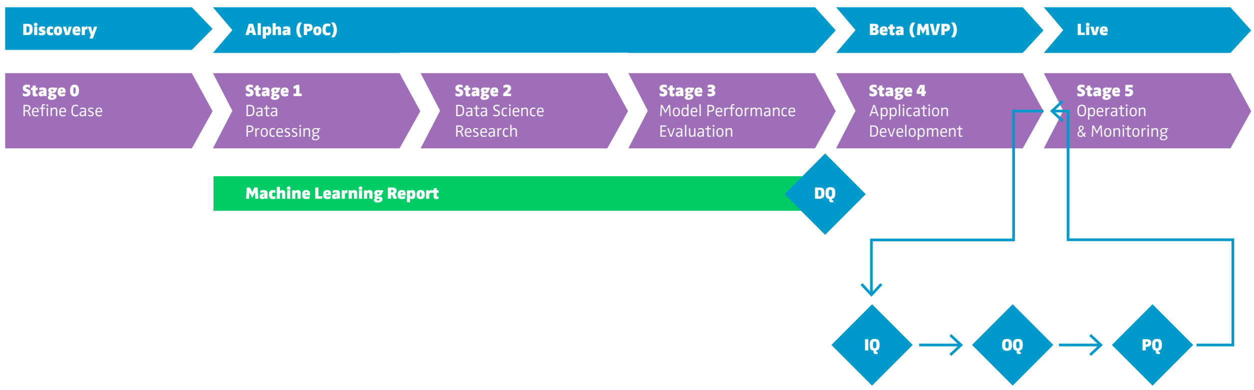

Figure 3: AI as part of the GMP development process. The Machine Learning Report is used to document data processing, AI architecture, models and evaluation. This is reviewed and approved as part of design qualification (DQ). The resulting AI model is then tested again as part of operational and performance qualification (OQ/PQ).

The following four key areas act as the bedrock for an AI implementation framework that can satisfy regulatory expectations and AI successful practices alike:

Model lifecycle management

The lifecycle of AI models must be governed by well-defined processes covering development, validation, deployment, maintenance, and eventual decommissioning. Regulatory bodies stress the importance of rock-solid protocols for managing model updates – including assessing the impact of any changes on product quality and process performance. 'Lifecycle transparency' is an ethos that supports both internal quality assurance and external regulatory auditability.

Data governance

Effective AI models are only as good as the datasets they are trained on. Regulatory guidelines therefore highlight the need for stringent data governance – especially when AI-generated data feeds into critical decision-making processes. That means companies must ensure full traceability and auditability of input data and AI outputs. This includes clear policies on data retention, quality thresholds, version control, and human oversight mechanisms.

Control strategy

An overarching control strategy is essential if businesses want to ensure that AI systems remain predictable, safe, and within specified operational parameters. This includes defining monitoring metrics, thresholds for performance deviations, and escalation paths for human intervention. In GxP contexts, explainability and controllability are not optional; AI outputs must remain interpretable.

Documentation and validation

Thorough documentation is the backbone of any thoroughly validated system. Regulatory guidance and good industry practice require ironclad documentation that covers system architecture, training data provenance, model validation methodology, software versioning, and performance monitoring. This practice not only supports regulatory submissions but also mitigates operational risks by making AI system behaviour transparent and reproducible.

Successful practices: 8 steps to successful AI deployment

The foundational key areas listed above pave the way for a comprehensive, systematic framework for AI implementation – one that is scientifically sound, operationally feasible, and regulatory-compliant.

To translate these principles into actionable deployment, we recommend adopting the following successful practices across the AI lifecycle:

1. Emphasise data and labelling quality

Large, unbiased datasets with high-quality labels are essential for training and evaluation of AI models. The process of obtaining reference labels should be thoroughly documented, including details about the qualifications of human annotators involved. Any criteria used for data removal should also be clearly documented, along with how confounding variables were handled. The data must be representative of the target data distribution.

2. Implement strong machine learning practices

Organisations should establish formal guidelines for machine learning development and ensure all data scientists adhere to them consistently. This includes implementing proper data splitting strategies that separate training, tuning, and testing datasets appropriately. Successful practices for data collection, preprocessing, and outlier removal should be followed rigorously – while all experiments and results need to be documented comprehensively. Version control and cross-validation techniques should be used for code, models, and data to maintain consistency.

3. Use simple, transparent, and interpretable models

When developing AI for critical systems, simpler models should be favoured as they tend to be more robust in real-world applications. Models need to be evaluated for their ability to withstand slight perturbations in the data, while model explainability should be prioritised to help understand outputs – and the reasoning behind predictions. For more complex models, appropriate interpretability techniques should be applied to explain predictions. Where possible, interpretable models (like decision trees or linear regression) should be chosen over black-box alternatives.

4. Conduct thorough evaluation

Evaluation should focus on performance with unseen data rather than training data to better estimate real-world performance. Data should be properly split, while maintaining stratification and avoiding correlation issues between training and testing sets. Robustness and sensitivity analysis should focus on finding model limitations, while performance should be compared against simple baselines, human per-formance, and state-of-the-art solutions alike. Performance analysis on out-of-distribution data is also crucial, as this will help demonstrate how models behave with unexpected inputs.

5. Use reproducible machine learning pipelines

All aspects of an AI model's training and testing should be automated to ensure consistent, reproducible results. Executable pipelines should be created for data preprocessing, feature selection, and hyperparameter optimisation to eliminate variability. Manual processes should be eliminated as they reduce reproducibility and might introduce inconsistencies in the workflow.

6. Manage data, model, and code history

Any data, model, and code changes should be tracked together, since they are interdependent components – compatibility between versions needs to be a priority.

7. Build out comprehensive documentation

Ground truth labels, data processing methods, and data distribution characteristics should all be thoroughly documented. Model validation approaches, software bug mitigation strategies, and code review processes need to be described in detail. Documentation should also cover sampling methods, model selection criteria, feature selection processes, and hyperparameter optimisation techniques.

8. Communicate results – and any uncertainties

The capabilities and limitations of any active AI model needs to be clearly communicated to users to prevent misuse and misunderstanding. Probabilities presented to users need to reflect true likelihoods, with techniques implemented to identify when input data differs significantly from training data, as this could affect model performance. Standardised label formats like "Model facts" should be considered to present model characteristics consistently.

For more detail on these successful practices, please refer to Zühlke's full report – How to build medical AI: Combining best practices from machine learning and medical device development. [16]

Key takeaways

Implementing AI in pharmaceutical manufacturing requires a structured, compliant framework that spans the full AI lifecycle – from development and validation to deployment and ongoing monitoring.

Key pillars here include:

- Robust model lifecycle management across the entire AI-enabled solution – including models, data and code
- Stringent data foundations and governance
- Clear control strategies
- Thorough documentation

Successful practices – like prioritising data quality, using interpretable models, automating reproducible pipelines, and communicating uncertainty – are essential for safe, scalable AI integration.

Sustainable scalability

The pathway to AI-enabled agility

With several real-world case studies already demonstrating a range of benefits, it's clear that AI has the potential to overcome many of pharmaceutical manufacturing's long-standing challenges – while also delivering innovation.

But success in this complex landscape requires a thoroughly strategic approach – one that carefully balances new technical capabilities with regulatory compliance and organisational readiness.

This is a balance well worth striking.

With AI set to become a core component of any agile manufacturing operation, pharmaceutical companies that implement this new technology today stand to gain substantial competitive advantages over those who wait.

The path to becoming a fully data-driven organisation may seem daunting. Attempting to act on and implement every AI capability simultaneously can be counterproductive, so it's vital to adopt an iterative, use case-driven approach.

This begins with a thorough data maturity assessment to identify and prioritise critical gaps – whether in data infrastructure, machine learning processes, or talent development.

Establishing a clear picture of organisational readiness enables a more targeted strategy and a pragmatic, documentable roadmap. By focusing on concrete use cases, organisations can measure the impact of their initiatives, build trust through demonstrable results, and ensure that efforts remain grounded in the realities of day-to-day operations, rather than abstract aspirations.

This phased, practical strategy can empower pharmaceutical companies to scale their AI and data capabilities in a way that weighs innovation and operational stability equally – positioning them for success in an increasingly digital future.

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